


----- Prompt and favorable consideration of this Preliminary Amendment is respectfully requested. -----

Dated: July 25, 2003

Respectfully submitted,

By


Andrea G. Reister

Registration No.: 36,253

COVINGTON & BURLING

1201 Pennsylvania Avenue, N.W.

Washington, DC 20004-2401

(202) 662-6000

Version With Markings to Show Changes Made

Page 1, first sentence of the specification, please amend the first paragraph, as follows:

This application is a continuation of application no. 10/278,011, filed October 23, 2002, which is a continuation of application no. 10/120,492, filed April 12, 2002, which is continuation of application no. 09/920,862, filed August 3, 2001 (U.S. Patent No. 6,403,114), which is a continuation of application no. 09/578,717, filed May 26, 2000 (U.S. Patent No. 6,290,983), which is a continuation of application no. 09/263,098, filed March 5, 1999 (U.S. Patent No. 6,110,503), which is a continuation of application number 09/071,865, filed May 4, 1998 (U.S. Patent No. 5,916,598), which is a continuation of 08/850,679, filed May 2, 1997 (U.S. Patent No. 5,792,477), which claims priority to provisional application no. 60/041,551, filed May 7, 1996, the entirety of which is hereby incorporated by reference.

Page 5, paragraph beginning at line 19, please amend the paragraph as follows:

In Ramstack *et al.*, U.S. Application No. 08/298,787 (now U.S. Patent No. 5,650,173), the entirety of which is incorporated herein by reference, a process was disclosed for preparing biodegradable, biocompatible microparticles comprising a biodegradable, biocompatible polymeric binder and a biologically active agent, wherein a blend of at least two substantially non-toxic solvents, free of halogenated hydrocarbons, was used to dissolve both the agent and the polymer. The solvent blend containing the dissolved agent and polymer was dispersed in an aqueous solution to form droplets. The resulting emulsion was then added to an aqueous extraction medium preferably containing at least one of the solvents of the blend, whereby the rate of extraction of each solvent was controlled, whereupon the biodegradable, biocompatible microparticles containing the biologically active agent were formed. The preferred active agents for encapsulation by this process were norethindrone, risperidone, and testosterone and the preferred solvent blend was one comprising benzyl alcohol and ethyl acetate.

Page 6, the paragraph beginning at line 3, please amend as follows:

Risperidone encapsulated in microparticles prepared using a benzyl alcohol and ethyl

-----acetate solvent system is also described in Mesens et al., U.S. Patent Application 08/403,432 -----
(now U.S. Patent No. 5,688,801), the entirety of which is also incorporated herein by reference.

Page 24, the paragraph beginning at line 23, please amend as follows:

A preferred type of mixing means is a static mixer and a preferred method of encapsulating the active agent to form the controlled release microparticles of the present invention involves the use of such a static mixer. Preferably the combined organic and aqueous phases are pumped through a static mixer to form an emulsion and into a large volume of quench liquid, to obtain microparticles containing the active agent encapsulated in the polymeric matrix material. An especially preferred method of mixing with a static mixer in the process of the present invention is disclosed by Ramstack *et al.* in U.S. Application No. 08/338,805 (now U.S. Patent No. 5,654,008), the entirety of which is incorporated herein by reference.